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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CORNING INCORPORATED
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CORNING, NY 14831

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,242	FANG ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-8,10-18,27 and 42-66* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,10-18 and 42-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2009 has been entered.

Response to Amendment

2. Applicant's amendment of claims 1, 42, 49, 57, is acknowledged and has been entered.

3. Applicant's addition of claims 62-66 is acknowledged and has been entered.

4. Applicant's cancellation of claim 9 is acknowledged and has been entered.

5. Claims 1, 4, 5, 10-18, 42-66 are currently pending and under examination.

6. Claims 3, 6-8, 27, are withdrawn.

7. The Office Action mailed July 22, 2009 is withdrawn, and the following action has been issued, in order to address additional issues that were not addressed in the prior office action.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. while the disclosure discusses incubating the arrays in a humid chamber to enable possible lateral distribution of lipid molecules, there is no indication that this would in fact enable lateral fluidity of the lipids. Furthermore, the disclosure also discloses that in tests of membrane microarray stability, lateral fluidity was accomplished by derivatization of the substrate surface with γ-aminopropysilane (para. 0042), and not by incubation in a humid chamber.

Claims 62-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the disclosure fails to provide support for the limitations of claims 62, 63 for incubating the array in the humid chamber before incubating the array in a composition comprising a toxin binding moiety, or even that the incubation of the array in a humid chamber and the incubation of the array in a composition comprising a toxin binding moiety are two separate steps. While applicants refers to p. 12-13 for support for these limitations, this section appears to discuss incubating the array with a labeled toxin after incubation of the array in a humid chamber, wherein the toxin-binding moieties appear to already be part of the array.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 42-48, 53, 54, are rejected under 35 U.S.C. 102(e) as being anticipated by Fang et al. [US 2002/0094544].

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claims 42, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with a amine presenting molecule (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein such as G-protein coupled receptors or G-proteins (para. 0009), which would bind to chemical toxins. Fang et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for an hour (para. 0130).

12. With respect to claims 43-44, Fang et al. further teach that the analyte may be labeled and detected by fluorescence (para. 0103).

13. With respect to claim 45, Fang et al. teach washing to remove unbound targets (para. 0104).

14. With respect to claim 46, Fang et al. teach that the array of microspots is incubated with labeled cognate target and an unlabeled target compound, and the binding event between the unlabeled target compound and the probe is determined by measuring a decrease in the signal of the label due to competition between the cognate labeled target and the unlabeled target compound for the probe (para. 0033).

15. With respect to claim 47, Fang et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0033), wherein the target is unlabeled (para. 0033).

16. With respect to claim 48, Fang et al. teach measuring a change in refractive index (para. 0033).

17. With respect to claim 53, Fang et al. teach coating with γ-aminopropylsilane (para. 0015).

18. With respect to claim 54, the amines used by Fang et al. may be polyethyleneimine (para. 0068).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 1, 4-5, 10-16, 18, 49, 52, 57-58, 60-66 are rejected under 35 U.S.C. 103(a) as being obvious over Fang et al. [US 2002/0094544] in view of Löfås [US 5,922,594].

With respect to claims 1, 4, 5, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein (para. 0009), and further teach detection of a binding event with the membrane bound protein. Fang et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for a hour (para. 0130). Although Fang et al. do not specify the incubation would be to enable lateral fluidity of the lipids, applicants have not specified any other requirement to enable lateral fluidity of the lipids other than to incubate the array in a humid chamber, this limitation would read on the method of Fang et al. since Fang et al. do teach the step of incubating the array in a humid chamber. Fang et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample

Löfås, however, teaches liposomes containing ganglioside G_{M1} for detecting cholera toxins in a sample (column 5, 6, example 1). Löfås further teaches that this allows for the detection and determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as G_{M1}, as suggested by Löfås et al., in order to be able to detect the presence of cholera toxin in a sample in a system similar to biological membranes.

21. With respect to claims 10, 11, 14, Fang et al. further teach that the analyte may be labeled and detected (para. 0103).

22. With respect to claim 12, Fang et al. teach detecting a physical change in physical properties at the interface due to a binding event between the target and the probe (para. 0033).

23. With respect to claim 13, Fang et al. teach unlabeled target (para. 0033).

24. With respect to claim 15, Fang et al. teach synthetic or natural analytes, while Umek et al. analytes which may be toxins (para. 0060), as discussed above.

25. With respect to claims 16, 18, Fang et al. teach glass slides (para. 0012).

26. With respect to claim 17, Fang et al. teach porous substrates (para. 0067).

27. With respect to claims 49, 57, 62, Fang et al. teach an array comprising a plurality of biological membrane microspots associated with a surface of a substrate in an environment exposed to air under ambient or controlled humidities (para. 0009), wherein the surface is coated with a amine presenting molecule such as thioalkyl amine (para. 0016-0017). The biological membrane microspots comprise a membrane bound protein such as G-protein coupled receptors or G-proteins (para. 0009), which would bind to chemical toxins. Fang et al. further teach detection of a binding event using the probe array after incubation in a humid chamber at room temperature for a hour (para. 0130). Fang et al., however, do not specify monitoring for binding activity of at least one of the biological lipid membranes with toxin in a sample.

Löfås, however, teaches liposomes containing ganglioside G_{M1} for detecting cholera toxins in a sample (column 5, 6, example 1). Löfås further teaches that this allows for the detection and determination of the specific activity of the lipid bilayer for binding to cholera toxins, thus providing important information of binding of cholera toxin with biological membranes (column 6, lines 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as G_{M1}, as suggested by Löfås et al., in order to be able to detect the presence of cholera toxin in a sample in a system similar to biological membranes.

28. With respect to claims 51, 55, 58, 60, 61 as discussed above, the amines used by Fang et al. may be γ-aminopropylsilane (para. 0015).

29. With respect to claims 52, 56, as discussed above, the amines used by Fang et al. may be polyethyleneimine (para. 0068).

30. With respect to claims 63-65, Löfås teach the detection of cholera toxin, which is a bacterail toxin, by binding to ganglioside G_{M1}.

31. With respect to claim 66, Fang et al. teach lipids printed on GAPS substrate (para. 0141), and would therefore have a mobile fraction of about 0.5, based on applicants own admission (see specification, para. 0041).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-48, 53, 54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 54-70 of copending Application No. 09/974,415 [published as US 2002/0094544]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite a method for detecting a binding event comprising providing a substrate with a plurality of biological membrane microspots comprising aminopropylsilane and proteins for binding and detecting binding using labeled targets and wherein the array is incubated under controlled humidity (claims 54, 55, 79).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

32. Applicant's arguments filed April 30, 2009 have been fully considered but they are not persuasive. With respect to applicant's arguments that Fang et al. fail to teach toxin-binding moieties and that G-protein coupled receptors are not toxin binding moieties, the Office notes that applicants clearly disclose G-protein coupled receptors as examples of toxin binding

moieties in the disclosure, as seen in para. 0006 and 0009, as in the background and summary. Since the claims must be read in light of the specification, and since applicants clearly state that the toxin-binding moieties include G protein coupled receptors, the G-protein coupled receptors of Fang et al. would read on the claims. Should applicants arguments rely on the fact that Fang et al. does not use the G-protein coupled receptors for the purpose of toxin binding moieties, the Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the G-protein coupled receptors of Fang et al. are capable of binding to toxins, and since the claims do not recite the actual step of binding the receptors to toxins, thus resulting in an active method step, therefore, by applicants own admission, the claims would read on the prior art.

33. With respect to applicant's arguments with regard to incubating the array in a humid chamber to enable lateral fluidity of the lipids, the Office acknowledges that Fang et al. do not teach incubating the array in a humid chamber for the sole purpose of enabling lateral fluidity of the lipids. However, the Office notes that applicants also do not appear to have support for this intended use as well. While applicants suggest incubating arrays in a humid chamber may enable possible lateral **distribution**, this does not necessarily involve enabling lateral **fluidity**, or even that lateral fluidity would result from incubation of the arrays. Furthermore, Fang et al. teach incubating the arrays in a humid chamber under the same conditions disclosed by applicant, and therefore, the incubation of the arrays in Fang et al. would also result in enablement of lateral fluidity, unless additional steps which have not been recited are required.

Conclusion

34. No claims are allowed.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Primary Examiner, Art Unit 1641